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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BRADLEY N. RUBEN, PC 463 FIRST ST, SUITE 5A HOBOKEN, NJ 07030			EXAMINER WALKER, AMANDA H	
			ART UNIT 4134	PAPER NUMBER
			MAIL DATE 10/17/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/544,260

Applicant(s)

BLUNN ET AL.

Examiner

Amanda H. Walker

Art Unit

4134

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☒ Claim(s) 8, 11, and 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8-3-2005.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

Specification

The disclosure is objected to because of the following informalities: the phrase "hip replacement in" (page 1, line 18) appears to be a typo. For the purpose of further examination, the Office interprets "hip replacement in" to mean –hip replacement. In".

Appropriate correction is required.

Claim Objections

Claim 8 is objected to because of the following informalities: the word "with" appears to be a typo. For the purpose of further examination, the Office interprets "with" to mean –which—. Appropriate correction is required.

Claim 11 is objected to because of the following informalities: the word "celulose" appears to be a typo. For the purpose of further examination, the Office interprets "celulose" to mean --cellulose--. Appropriate correction is required.

Claim 28 is objected to because of the following informalities: the abbreviation "MP" appears to be a typo. For the purpose of further examination, the Office interprets "MP" to mean --MPa--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is indefinite because it is missing a reference back to a parent claim. For the purpose of further examination, the Office interprets claim 13 to depend from claim 1.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites the limitation "the membrane". There is insufficient antecedent basis for this limitation in the claim.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 recites the limitation " the multiple spacers ". There is insufficient antecedent basis for this limitation in the claim.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 recites the limitation " configuration ". There is insufficient antecedent basis for this limitation in the claim.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 is indefinite because the preamble states that the method is for making a surgical kit, while the limitations appear to be a method of treating a patient using the surgical kit. The scope is therefore unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson (U.S. Patent No. 2,785,673).

Anderson teaches surgical kit having a prosthetic femoral head (FIGS 1-20) that is inherently sized and shaped appropriately with reference to the weight of a patient. Anderson also teaches a reamer (FIG. 18).

Claims 1, 5, 7, 13, 15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Maumy et al. (U.S. Patent No. 5,507,828).

Maumy et al. teaches a surgical kit having a prosthetic femoral head (1:10-11) appropriate for the weight of a patient (FIGS. 1-3). Maumy et al. also discusses that the socket has been prepared/reamed (3:66). This inherently requires a reaming tool. Maumy et al. also teaches multiple spacers. The spacers 40 and 41 may be resorbable (4:10-20) or the outer shell spacers 1b and 1e may be a rigid metal (2:25-35 and 4:1-5). Porosity/ permeability inherently accompanies the property of resorbability. Maumy et al. also teaches a plastic inner shell/membrane (2:25-35) which is inherently less rigid than the metal outer shell/spacers.

Claims 20, 22, 24, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Maumy et al. (U.S. Patent No. 5,507,828).

Maumy et al. teaches a surgical kit having a prosthetic femoral head (1:5-15). Maumy et al. also discusses that the socket has been prepared/reamed (3:66). This inherently requires a reaming tool that would inherently be complementary to the reamer. Maumy et al. also teaches multiple spacers. The spacers 40 and 41 may be resorbable (4:10-20) or the outer shell spacers 1b and 1e may be made of a rigid metal (2:25-35 and 4:1-5). Maumy et al. also teaches a plastic inner shell/membrane (2:25-35) which is inherently less rigid than the metal outer shell/spacers.

Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Anderson (U.S. Patent No. 2,785,673).

Anderson teaches a method of hemiarthroplasty comprising; providing prosthetic femoral head and a reamer, the femoral head structure being complementary to that of the reamer (FIG. 16 and 17), reaming a socket (8:65-70), and fitting the femoral head into reamed acetabulum socket. Reaming would inherently expose cancellous bone, considering that the outer layer of cortical bone is thin. The liquid between head and socket is inherently at a pressure of 0.01-5MPa, considering that the range is very wide and that pressures in that area are known to vary significantly (by patient and by pinpointed acetabular location) and encompass that range, with or without a prosthetic

device. It is known that such pressures stimulate cartilage formation, as evidenced by Ishihara et al. (abstract).

Claims 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Harris et al. (U.S. Patent Application Publication No. 2002/0156536).

Harris et al. teaches a surgical kit including a membrane/acetabular cup that may be "press-fit" into the bone. This type of procedure inherently involves reaming and a reamer (para. 0061). Considering that Harris et al. teaches that the clearance between the femoral ball head and the acetabular socket may be 2-10 mm, it is also implicit that the reamer would be on the range of 2-10 mm larger than the ball head (para. 0055).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 6, 8-12, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (U.S. Patent No. 2,785,673) as applied to claim 1 above and further in view of Brown et al.

Anderson teaches the basic claimed surgical kit as applied above.

Regarding Claims 4, 6, 8, 14, and 16: Anderson does not teach a membrane with all of the limitations and properties listed in the instant claims. However, Brown et al. teaches a resorbable (p.12: line 17) continuous, porous membrane (FIG. 1). The membrane is adapted to deliver growth factors/stem cells/fibroblasts or chondrocytes (p.3: lines 2-10). Anderson and Brown et al. are combinable because they are from the same field of endeavor, namely, biocompatible implants (Brown et al., p. 1: lines 1-10). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the femoral kit taught by Anderson with the membrane taught by Brown et al., and one would have been motivated to do so in order to encourage tissue growth (p. 1: lines 1-10).

Regarding Claims 9-12: Anderson does not teach a membrane with all of the limitations and properties listed in the instant claims. However, Brown et al. teaches a membrane that has fibrous materials enclosed within a collagen gel (FIG 4, p.12: lines 30-32, and p.13: lines 1-5). The gel is inherently deformable. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the femoral kit

taught by Anderson with the membrane taught by Brown et al., and one would have been motivated to do so in order to encourage tissue growth (p. 1: lines 1-10).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (U.S. Patent No. 2,785,673) as applied to claim 1 above and further in view of Harris et al. (U.S. Patent Application Publication No. 2002/0156536).

Anderson teaches the basic claimed surgical kit as applied above.

Anderson does not teach that the reamer is at most 5mm greater than the femoral head. However, Harris et al. teaches a clearance between a ball head and an acetabular socket that may be 2-10 mm (para. 0055). It is therefore implicit that the reamer would be on the range of 2-10 mm larger than the ball head. Anderson and Harris et al. are combinable because they are from the same field of endeavor, namely, hip prostheses. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the reamer taught by Anderson with the size taught by Harris et al., and one would have been motivated to do so in order to be sure that the ball head could fit into the reamed acetabular socket.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mosseri (U.S. Patent No. 6,231,611) in view of Averill et al. (U.S. Patent No. 5,593,451).

Mosseri teaches a surgical kit with a modular reamer (FIG. 3) having a shaft and substantially part spherical heads with cutting teeth. The cutting teeth may face outwardly or inwardly (FIG. 3 and FIG. 6).

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Mosseri does not teach that the inward and outward cutting teeth are on the same reamer head. However, Averill et al. teaches a cylindrical reamer that has inwardly facing and outwardly facing teeth (3:35-45). Mosseri and Averill et al. are combinable because they are from the same field of endeavor, namely, hip prostheses. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to consolidate the reamers taught by Mosseri to be double sided like the reamer taught by Averill et al., and one would have been motivated to do so in order to speed the surgery.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (U.S. Patent No. 2,785,673) in view of Harris et al. (U.S. Patent Application Publication No. 2002/0156536).

Anderson teaches a reamer and a complementary femoral head (FIGS. 17 and 18).

Anderson does not teach that the reamer is at most 5mm greater than the femoral head. However, Harris et al. teaches a clearance between a ball head and an acetabular socket that may be 2-10 mm (para. 0055). Therefore, it is implicit that the reamer would be on the range of 2-10 mm larger than the ball head. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the reamer taught by Anderson with the size taught by Harris et al., and one would have been motivated to do so in order to be sure that the ball head could fit into the reamed acetabular socket.

Claims 21, 23, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (U.S. Patent No. 2,785,673) in view of Harris et al. as applied to claim 20 and further in view of Brown et al. (WO-02/50242-A2).

Anderson and Harris et al. teach the basic claimed surgical kit as applied above.

Anderson does not teach a membrane with all of the limitations and properties listed in the instant claims. However, Brown et al. teaches a resorbable (p.12: line 17) continuous, membrane (FIG. 1) in the form of a collagen gel (FIG 4 and p.12: lines 30-32, and p.13: lines 1-5). A gel is inherently deformable. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to coat the femoral head taught by Anderson with the membrane taught by Brown et al., and one would have been motivated to do so in order to encourage tissue growth (p. 1: lines 1-10). The membrane would then implicitly be complementary to the femoral head.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mosseri (U.S. Patent No. 6,231,611) in view of Averill et al. (U.S. Patent No. 5,593,451).

Mosseri teaches a reaming procedure for a ball and socket joint (FIGS. 1-18), comprising forming an access tunnel in a natural ball part of joint (FIG. 1), providing a modular shell reamer having a separable substantially part-spherical head and a shaft (FIG. 1), introducing the shaft into the tunnel and introducing the reamer head separately (FIG. 1), coupling the inserted shaft and head in situ (FIG. 2), and reaming both the socket surface and the ball surface (FIGS. 3 and 6).

Mosseri does not teach that the inward and outward cutting teeth are on the same reamer head. However, Averill et al. teaches a cylindrical reamer that has inwardly facing and outwardly facing teeth (3:35-45). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to consolidate the reamers taught by Mosseri to be double sided like the reamer taught by Averill et al., and one would have been motivated to do so to speed the surgery.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mosseri (U.S. Patent No. 6,231,611) in view of Averill et al. (U.S. Patent No. 5,593,451).

Mosseri teaches a reamer (FIG. 3) having a shaft and a substantially part spherical heads with cutting teeth. The head and shaft are separable (FIG. 1). The cutting teeth may face outwardly or inwardly (FIG. 3 and FIG. 6).

Mosseri does not teach that the inward and outward cutting teeth are on the same reamer head. However, Averill et al. teaches a cylindrical reamer that has inwardly facing and outwardly facing teeth (3:35-45). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to consolidate the reamers taught by Mosseri to be double sided like the reamer taught by Averill et al., and one would have been motivated to do so to speed the surgery.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (U.S. Patent No. 2,785,673).

Anderson teaches a surgical procedure and a method of making a surgical kit comprising; providing a prosthetic femoral head and a complementary reamer (FIG. 16 and 17) that is reamer is inherently adapted to ream cancellous bone (considering that it can ream through the denser cortical bone), and determining the patient's weight (inherent to all medical procedures).

Anderson does not explicitly teach estimating the contact area of the hip joint needed to ensure hydrostatic pressure in range of 0.01-5 MPa and picking an appropriate femoral head to apply such a pressure. However, at the time of the invention, it would have been obvious to a person having ordinary skill in the art to use a femoral head that is sized appropriately to induce such a broad range of pressure, and one would have been motivated to do so in order to provide a comfortable fit and mimic the natural pressures that occur in that particular joint space.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harris et al. (U.S. Patent Application Publication No. 2002/0156536) as applied to claim 32 and further in view of Babalola et al. (U.S. Patent No. 6,494,916).

Harris et al. teaches the basic surgical kit as applied above.

Harris et al. does not teach that the kit has multiple spacers. However, Babalola et al. teaches that the kit has multiple solid circular objects/spacers 32 (FIG. 2). Harris et al. and Babalola et al. are combinable because they are from the same field of endeavor, namely, hip prostheses. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the surgical kit taught by

Harris et al. with the spacers taught by Babalola et al., and one would have been motivated to do so in order to provide a buffer between a lubrication liquid and the acetabular component (Babalola et al., 8:1-5).

Other prior art considered applicable to the instant claims but not used in these rejections can be found in the enclosed document entitled "Notice of References Cited".

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda H. Walker whose telephone number is (571) 270-3296. The examiner can normally be reached on 9-4, M-Th, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on (571) 272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AHW
10-11-07

A handwritten signature in black ink, appearing to read 'M. Eashoo', with a stylized flourish at the end.

MARK EASHOO, PH.D.
SUPERVISORY PATENT EXAMINER

14/04/07